

October 28, 2004

Mr. Robert Johnson, Manager
Radiation Health and Toxic Agents Branch
Cabinet for Health Services
275 East Main Street
Frankfort, KY 40621-0001

Dear Mr. Johnson:

We have reviewed the proposed changes to the Kentucky regulations, 902 KAR 100:072 "*Use of Radionuclides in the Healing Arts*", that were submitted to meet the changes to 10 CFR 35, via your September 27, 2004 letter. Our review and comments are in response to the State's request for Nuclear Regulatory Commission (NRC) evaluation of the changes to Kentucky's radiation control rules that incorporated the amendments identified on the State's Regulation Data Sheet (SRS). These regulations were reviewed by comparison to the equivalent NRC rules in 10 CFR Parts 20, 32 and 35. We discussed our review of the regulations with Matthew McKinley of your staff on October 8, 2004, who explained that some of the provisions covered by 10 CFR 35, are covered under 902 KAR 100:10. These applicable sections were also reviewed and added to your initial regulation package. Mr. McKinley also provided information regarding the pending changes to Parts 010, 019 and 073 mentioned in the attached comment chart.

As a result of our review, we have three comments. Please provide a final, amended version of your regulations, showing the location of any changes made in response to our comments. If there are any comments which Kentucky believes are in error, the State should identify the section of the regulations that meet the designated compatibility category. Please note that we have limited our review to the items required for compatibility and/or health and safety.

The SRS Data Sheet summarizes our knowledge of other Kentucky regulations. Please let us know if you note any inaccuracies or have any comments on the information contained in the SRS Data Sheet. This letter, including the SRS Data Sheet, is posted on the STP Web Site: <http://www.hsrdrnrl.gov/nrc/rulemaking.htm>.

If you have any questions regarding the comments, the compatibility and health categories, or any of the NRC regulations used in the review, please contact me or Sheri Minnick, Regional Agreement States Officer, at (610) 337-5358 or SAM9@NRC.GOV.

Sincerely,

IRA By K.N. SCHNEIDER FOR

Josephine M. Piccone, Deputy Director
Office of State and Tribal Programs

Enclosures:
As stated

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OFFICE	Region I	STP	OGC	STP:DD
NAME	SMinnick	JZabko	STreby	KNSchneider for JMPiccone
DATE	10/20/04*	10/20/04*	10/27/04*	10/28/04*

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COMPATIBILITY COMMENTS ON KENTUCKY REGULATIONS

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
1	Pending Part 019	20.1301 (a) and (c)	2002-2	A	<p>Dose limits for individual members of the public</p> <p>The State has referenced new rule text for this section that is currently undergoing revision and has not yet been approved in the State. Consequently, there is no compatible part in the State rule text for this section at this time.</p> <p>The State needs to finish the promulgation process for this rule section and submit it to the NRC for review to achieve compatibility for this section in amendment 2002-2.</p>
2	Pending Part 010	35.2	2002-2	B	<p>Definitions</p> <p>Authorized medical physicist Authorized nuclear pharmacist Authorized user Medical use Prescribed dosage Prescribed dose Radiation safety officer Sealed source Treatment site</p> <p>The State has referenced new rule text for this section that is currently undergoing revision and has not yet been approved in the State. Consequently, there is no compatible part in the State rule text for this section at this time.</p> <p>The State needs to finish the promulgation process for this rule section and submit it to the NRC for review to achieve compatibility for this section in amendment 2002-2.</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
3	Pending Part 072	35.6	2002-2	C	<p>Provisions for the Protection of human research subjects</p> <p>The State has referenced new rule text for this section that is currently undergoing revision and has not yet been approved in the State. Consequently, there is no compatible part in the State rule text for this section at this time.</p> <p>The State needs to finish the promulgation process for this rule section and submit it to the NRC for review to achieve compatibility for this section in amendment 2002-2.</p>

STATE REGULATION STATUS

State: Kentucky

[One amendment reviewed is identified

by a i at the beginning of each equivalent NRC regulation.]

Tracking Ticket Number: 4-270

Date: October 28, 2004

NRC Chronology Identification	FR Notice (State Due Date)	RATS ID	Proposed (P) / Final (F) ¹ Rule / ML # ⁵	NRC Review / Y, N ² / Date / ML # ⁵	Final State Regulation ¹ (Effective Date)
Safety Requirements for Radiographic Equipment-Part 34	55 FR 843; (1/10/94)	1991-1	F	N 3/15/96	4/11/94
ASNT Certification of Radiographers-Part 34	56 FR 11504; (none)	1991-2			Not required ³
Standards for Protection Against Radiation-Part 20	56 FR 23360; 56 FR 61352; 57 FR 38588; 57 FR 57877; 58 FR 67657; 59 FR 41641; 60 FR 20183; (1/1/94)	1991-3	F P	N 2/16/97 N 4/17/98	4/11/94
Notification of Incidents-Parts 20, 30, 31, 34, 39, 40, 70	56 FR 64980; (10/15/94)	1991-4	F	N 3/15/96	4/19/95
Quality Management Program and Misadministrations-Part 35	56 FR 34104; (1/27/95)	1992-1	F	N 3/15/96	4/11/95
Eliminating the Recordkeeping Requirements for Departures from Manufacturer's Instructions- Parts 30,35	57 FR 45566; (none)	1992-2			Not required ³
Decommissioning Recordkeeping and License Termination: Documentation Additions [Restricted areas and spill sites]-Parts 30, 40	58 FR 39628; (10/25/96)	1993-1	F	N 3/15/96	4/19/95
Licensing and Radiation Safety Requirements for Irradiators-Part 36	58 FR 7715; (7/1/96)	1993-2			Not applicable SECY-95-112 ⁴
Definition of Land Disposal and Waste Site QA Program-Part 61	58 FR 33886; (7/22/96)	1993-3			Not applicable SECY-95-112 ⁴
Self-Guarantee as an Additional Financial Mechanism-Parts 30, 40, 70	58 FR 68726; 59 FR 1618 (none)	1994-1	F	N 3/15/96	Not required ³ 4/19/95
Uranium Mill Tailings Regulations: Conforming NRC Requirements to EPA Standards-Part 40	59 FR 28220; (7/1/97)	1994-2			Not required ³
Timeliness in Decommissioning Material Facilities-Parts 30, 40, 70	59 FR 36026; (8/15/97)	1994-3	F	N 4/17/98	8/20/97
Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use-Parts 30, 32, 35	59 FR 61767; 59 FR 65243 60 FR 322; (1/1/98)	1995-1	F	N 4/17/98	8/20/97
Frequency of Medical Examinations for Use of Respiratory Protection Equipment-Part 20	60 FR 7900; (3/13/98)	1995-2	F	N 4/17/98	1/14/97
Low-Level Waste Shipment Manifest Information and Reporting-Parts 20, 61	60 FR 15649; 60 FR 25983 (3/1/98)	1995-3	P ML013250155	N 2/7/02 ML020420112	
Performance Requirements for Radiography Equipment-Part 34	60 FR 28323; (6/30/98)	1995-4			4/19/95
Radiation Protection Requirements: Amended Definitions and Criteria-Parts 19, 20	60 FR 36038; (8/14/98)	1995-5	F	Y 4/17/98	11/14/97

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			P	N 4/17/98	9/11/00
Clarification of Decommissioning Funding Requirements-Parts 30, 40, 70	60 FR 38235; (11/24/98)	1995-6	P	N 6/21/00	9/11/00
Medical Administration of Radiation and Radioactive Materials-Parts 20, 35	60 FR 48623; (10/20/98)	1995-7			
10 CFR Part 71: Compatibility with the International Atomic Energy Agency-Part 71	60 FR 50248; 61 FR 28723 (4/1/99)	1996-1	F	Y 6/21/00	
One Time Extension of Certain Byproduct, Source and Special Nuclear Materials Licenses- Parts 30, 40, 70	61 FR 1109; (none)	1996-2			Not required ³
Termination or Transfer of Licensed Activities: Recordkeeping Requirements-Parts 20, 30, 40, 61, 70	61 FR 24669; (6/17/99)	1996-3		N 6/21/00	9/11/00
Resolution of Dual Regulation of Airborne Effluents of Radioactive Materials; Clean Air Act- Part 20	61 FR 65120; (1/9/00)	1997-1	F	N 4/17/98	11/14/97
Recognition of Agreement State Licenses in Areas Under Exclusive Federal Jurisdiction Within an Agreement State-Part 150	62 FR 1662; (2/27/00)	1997-2	F ML010780156	N 3/30/01 ML010890409	2/2/01
Criteria for the Release of Individuals Administered Radioactive Material-Parts 20, 35	62 FR 4120; (5/29/00)	1997-3	F	N 4/17/98	11/14/97
Fissile Material Shipments and Exemptions-Part 71	62 FR 5907; (none)	1997-4			Not required ³
Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiography Operations-Parts 30, 34, 71, 150	62 FR 28948; (6/27/00)	1997-5	F ML010780156	Y 3/30/01 ML010890409	2/2/01
Radiological Criteria for License Termination-Parts 20, 30, 40, 70	62 FR 39058; (8/20/00)	1997-6	F	N 6/21/00	9/11/00
Exempt Distribution of a Radioactive Drug Containing One Microcurie of Carbon-14 Urea- Part 30	62 FR 63634; (1/02/01)	1997-7	F	N 4/17/98	11/14/97
Deliberate Misconduct by Unlicensed Persons-Parts 30, 40, 61, 70, 150	63 FR 1890; 63 FR 13773 (2/12/01)	1998-1	F	N 6/21/00	10/16/00
Self-Guarantee of Decommissioning Funding by Nonprofit and Non-Bond-Issuing Licensees- Parts 30, 40, 70	63 FR 29535; (none)	1998-2			Not required ³
License Term for Medical Use Licenses-Part 35	63 FR 31604; (none)	1998-3			Not required ³
Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations-Part 34	63 FR 37059; (7/9/01)	1998-4	F ML010780156	N 3/30/01 ML010890409	2/2/01
Minor Corrections, Clarifying Changes, and a Minor Policy Change-Parts 20, 35, 36	63 FR 39477; 63 FR 45393 (10/26/01)	1998-5			
Transfer for Disposal and Manifests: Minor Technical Conforming Amendment-Part 20	63 FR 50127; (11/20/01)	1998-6	P ML013250155	N 2/7/02 ML020420112	
Radiological Criteria for License Termination of Uranium Recovery Facilities-Part 40	64 FR 17506; (6/11/02)	1999-1			

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Requirements for Those Who Possess Certain Industrial Devices Containing Byproduct Material to Provide Requested Information-Part 31	64 FR 42269; (none)	1999-2			Not required ³
Respiratory Protection and Controls to Restrict Internal Exposure-Part 20	64 FR 54543; 64 FR 55524 (2/2/03)	1999-3			
Energy Compensation Sources for Well Logging and Other Regulatory Clarifications-Part 39	65 FR 20337; (5/17/03)	2000-1			
New Dosimetry Technology-Parts 34, 36, 39	65 FR 63749; (1/8/04)	2000-2			
Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material - Parts 30, 31, 32	65 FR 79162; (2/16/04)	2001-1	F Only Reviewed the license conditions for 32.52 (a) & (b)	Y 3/16/04 ML040770705	Only Reviewed the license conditions for 32.52 (a) & (b)
Revision of the Skin Dose Limit-Part 20	67 FR 1629; (4/5/05)	2002-1			
i Medical Use of Byproduct Material-Parts 20, 32, 35	67 FR 20249; (4/24/05)	2002-2	P ML04272062	Y 10/28/2004 ML043030121	
Financial Assurance for Materials Licensees – Parts 30, 40, 70	68 FR 57327 12/3/06	2003-1			
Compatibility With IAEA Transportation Safety Standards and Other Transportation Safety Amendments – Part 71	69 FR 3697; (10/01/07)	2004-1			

1. Or other generic Legally Binding Requirements.
2. (Y/N) Y means “Yes,” there are comments in the review letter that the State needs to address.
N means “No,” there are no comments in the review letter.
3. Not required means these regulations are not required for purposes of compatibility.
4. A State need not adopt a specific regulation if the State has no licensees that would be subject to that regulation. See: “Final Policy Statement on Adequacy and Compatibility of Agreement State Programs,” III.1. Time Frame for Adoption of Compatible State Regulations, p. 6, SECY-95-112, May 3, 1995.
5. ADAMS ML Number